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UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE and ASTRAZENECA LP, KBI INC. and KBI-E, INC., Plaintiffs and Counterclaim Defendants, v. DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC. Defendants and Counterclaim Plaintiffs.	07-CV-6790 (CM)(GWG) **ELECTRONICALLY FILED**

DRL DEFENDANTS' MEMORANDUM OF LAW
IN SUPPORT OF DRL'S MOTION FOR SUMMARY JUDGMENT

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- Exhibits to the Second Weinstein Declaration:

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2. U.S. Patent No. 5,900,424
3. U.S. Patent No. 5,690,960
4. Amendment and Response dated December 9, 1996 in the prosecution of U.S. Patent No. 5,900,424
5. Amendment and Response dated October 7, 1996 in the prosecution of U.S. Patent No. 5,690,960
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7. U.S. Patent No. 4,738,974
8. Supplemental Amendment dated October 1, 1998 in the prosecution of U.S. Patent No. 5,900,424
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11. AstraZeneca's July 27, 2007 Complaint
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16. Letter from John Griem, Esq., dated June 16, 2008
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18. Copy of letter from John Griem, Esq., dated June 23, 2008 bearing Memo Endorsement by Judge Colleen McMahon, dated June 25, 2008.

- Second Declaration of Harry G. Brittain, Ph.D., FRSC (Filed in Support of DRL's Motion for Summary Judgment)

- Exhibits to the Second Brittain Declaration

A. Curriculum Vitae of Harry G. Brittain, Ph.D., FRSC

I. INTRODUCTION

The AstraZeneca plaintiffs still have no evidence of infringement.

Summary judgment should be granted because AstraZeneca cannot prove at least one element of each claim. AstraZeneca cannot show that DRL's omeprazole magnesium is more than 70% crystalline, AstraZeneca cannot show that DRL obtains omeprazole magnesium by the addition of water and AstraZeneca cannot show that DRL makes its finished product in the absence of organic solvents.

DRL has maintained all along that AstraZeneca has no evidence of infringement. This Court considered AstraZeneca's requests for additional infringement discovery and found that AstraZeneca's discovery requests smacked of a fishing expedition. Despite samples, detailed interrogatory answers, relevant documents from DRL's ANDA Application, relevant documents from DRL's Drug Master File, and the deposition of a witness with knowledge of DRL's process, AstraZeneca continues to complain that it lacks "sufficient information" to determine whether DRL infringes the patents-in-suit.

Enough is enough. This action should not have been brought and it is time for it to end. The Court gave AstraZeneca specific discovery and a time limit for deciding whether it would withdraw its case. AstraZeneca's time has come and gone.

There is no genuine issue of material fact, AstraZeneca cannot carry its burden of proving infringement and DRL respectfully urges the Court to grant DRL summary judgment and to dismiss the Complaint with prejudice.

This brief is organized as follows: DRL first presents the procedural posture of this case (Section II); then DRL briefly discusses certain relevant law (Section III.A-C); finally, DRL gives a detailed explanation on a claim-by-claim basis why there is no genuine issue of material fact regarding the alleged infringement of the patents-in-suit (Section III.D).

II. STATEMENT OF FACTS

A. AstraZeneca Admitted It Brought This Action To Obtain Discovery

AstraZeneca filed its Complaint on July 27, 2007. Exhibit 11.[1] Lacking evidence, AstraZeneca alleged on "information and belief" that the omeprazole magnesium capsules in DRL's abbreviated new drug application No. 78-878 infringed two AstraZeneca patents. Exhibit 11, ¶¶ 27 and 37. The two patents-in-suit are United States Patent 5,900,424 ("the '424 patent", Exhibit 2) and United States Patent 5,690,960 ("the '960 patent", Exhibit 3).

AstraZeneca candidly admitted in its Complaint that it brought this suit at least in part "to employ the judicial process and the aid of discovery" to obtain information about DRL's alleged infringement. Exhibit 11, ¶¶ 33 and 53.

B. DRL Has Asserted From The Start That AstraZeneca Has No Evidence Of Infringement

DRL has consistently maintained that AstraZeneca has no evidence of infringement. Before the September 21, 2007 Conference DRL suggested to the Court that this action could be resolved most expeditiously by an early motion for summary judgment. 2nd Weinstein Decl. ¶ 3; Exhibit 1. At the September 21st Conference the Court directed the parties to assume that DRL had made its motion. 2nd Weinstein Decl. ¶ 4. DRL produced samples on September 24, 2007 and AstraZeneca was ordered to test them by November 1, 2007. *Id.* ¶¶ 5-6. DRL responded to the 10 interrogatories that AstraZeneca was given leave to serve. *Id.* ¶ 6. After testing DRL's samples and reviewing DRL's Answers to Interrogatories, AstraZeneca reported at the November 7, 2007 Conference that AstraZeneca had no evidence of infringement. *Id.* ¶ 8. Predictably, AstraZeneca sought further discovery.

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[1] References to "Exhibit __" refer to Exhibits to the Second Declaration of Louis H. Weinstein ("2nd Weinstein Decl.") submitted herewith. References to "2nd Brittain Decl." refer to the Second Declaration of Dr. Harry Brittain, Ph.D., submitted herewith.

In response, the Court ordered AstraZeneca to submit a list of additional discovery and to justify for each-and-every-claim why the discovery was needed to show infringement. *Id.* ¶ 9. AstraZeneca submitted its 43 page "Explanation of Infringement Discovery" on November 19, 2007 (Exhibit 12) and DRL submitted its "Reply to AstraZeneca's Explanation of Infringement Discovery" (Exhibit 13) on November 28, 2007. 2nd Weinstein Decl. ¶¶ 11-12.

C. The Court Was Skeptical Of AstraZeneca's Requests But Ordered Limited Discovery

The Court ruled on AstraZeneca's discovery requests in the Court's "Rulings On Astra-Zeneca's Request For Infringement Discovery" ("Rulings", Exhibit 14). In the Rulings the Court found that AstraZeneca did not comply with the Court's direction that AstraZeneca justify its request for additional discovery on a claim-by-claim basis. Exhibit 14 ¶ 1. To the contrary, the Court found that AstraZeneca "had done nothing of the kind." *Id.* The Court also found that "Astra-Zeneca's discovery requests smack of a fishing expedition." Exhibit 14 ¶ 2 (emphasis supplied). Moreover, the Court found that AstraZeneca did not supply the Court "with anything other than an attorney's explanation about why the massive amount of discovery it seeks is necessary. . . ." Exhibit 14 ¶ 1.

Nonetheless, the Court ordered some of the discovery requested by AstraZeneca. First, the Court ordered DRL to produce the documents from DRL's ANDA application and Drug Master File as requested in AstraZeneca's Discovery Requests Nos. 1 and 2. Exhibit 14 ¶ 3. The Court also ordered DRL to produce a witness with knowledge of DRL's manufacturing process for a one day deposition. Exhibit 14 ¶ 9. DRL produced the additional documents. 2nd Weinstein Decl. ¶ 14. A DRL employee with knowledge of DRL's process was produced for deposition and the deposition was taken on May 23, 2008. 2nd Weinstein Decl. ¶ 15; Exhibit 15, Srinivas Transcript, p. 10, lines 13-21.

D. AstraZeneca Did Not Withdraw Its Action

The Court gave AstraZeneca 30 days following the completion of the additional discovery to decide whether it would withdraw its case. Exhibit 14 ¶ 9. If not, the Court gave DRL 30 days to move for summary judgment. *Id.* AstraZeneca did not withdraw its case and DRL is moving for summary judgment within the 30 days allowed by the Court. *Id.*

III. ARGUMENT

A. There Is No Genuine Issue Of Material Fact Concerning DRL's Alleged Infringement

"One of the principal purposes of the summary judgment rule is to isolate and dispose of factually unsupported claims or defenses. . . ." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24, 106 S. Ct. 2548, 2553 (1986). Summary judgment must be granted against a party who lacks the evidence sufficient to meets its burden of establishing an essential element of its case at trial. *Id.* at 322, 106 S. Ct. at 2552. The summary judgment movant must identify the basis of its motion and point to the parts of the record that demonstrate the absence of a genuine issue of material fact. *Id.* at 323, 106 S. Ct. at 2553. When the movant makes this showing the non-movant must come forward with specific facts which show that there is a genuine issue for trial. *Id.* at 324, 106 S. Ct. at 2553. Where there is no genuine disputed material fact and the movant is entitled to judgment as a matter of law, "the court should utilize the salutary procedure" of Rule 56 to avoid unnecessary expense to the parties and the waste of judicial resources. *Barmag Barmer Maschinenfabrik AG v. Mirata Mach., Ltd.*, 731 F.2d 831, 835 (Fed. Cir. 1984). Such action is appropriate here.

Like other actions, patent cases are amenable to summary judgment. *Id.* A defendant may move for summary judgment "at any time." Fed. R. Civ. P. 56(b); *see Innovad, Inc. v. Microsoft Corp.*, 260 F.3d 1326, 1329-30 (Fed. Cir. 2001); *Katz v. AIWA America, Inc.*, 818 F.

Supp. 730, 735 n.3 (D.N.J. 1993) (granting summary judgment of non-infringement where defendant served motion with its amended counterclaim). Because the burden of proving infringement is on the patentee, "an accused infringer seeking summary judgment of non-infringement may meet its initial responsibility either by providing evidence that would preclude a finding of infringement, or by showing that the evidence on file fails to establish a material issue of fact essential to the patentee's case." *Novartis Corp. v. Ben Venue Labs., Inc.*, 271 F.3d 1043, 1046 (Fed. Cir. 2001).

As discussed below, DRL meets its burden with respect to claim 1 of the '424 patent and claims 1 and 22 of the '960 patent because AstraZeneca has failed to establish that the omeprazole magnesium in DRL's finished capsules is more than 70% crystalline. DRL meets its burden with respect to claim 10 of the '960 patent because AstraZeneca has failed to establish that DRL forms a core with omeprazole magnesium that is at least 70% crystalline. DRL also meets its burden with respect to claim 10 of the '960 patent because the evidence of record establishes that DRL applies its subcoating using a solvent-based process and this precludes a finding that DRL's process is solvent free. Finally, DRL meets its burden with respect to claims 11 and 20 of the '424 patent because the evidence of record establishes that DRL obtains its omeprazole magnesium by the evaporation of organic solvent and this precludes a finding that DRL crystallizes omeprazole magnesium by the addition of water.

B. Infringement Requires Proof That Each Claim Element Is Met

Infringement requires proof that each claim element is met by the accused product or process. *Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1535 (Fed. Cir 1991) ("failure to meet a single limitation is sufficient to negate infringement of the claim"). AstraZeneca cannot prevail on any of its claims because, as discussed herein, proof is missing for at least one element of

each claim. AstraZeneca's lack of proof is the reason that AstraZeneca defied the Court's instruction to explain the need for additional discovery on a claim-by-claim basis.

C. The Court Only Needs To Consider Six Claims

Because a dependent claim includes all the elements of any claim from which it depends, a patent claim cannot be infringed if it depends from a claim that is not infringed. *Wahpeton Canvas Co., Inc. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n.9 (Fed. Cir. 1989). Here, most of the claims depend from at least one other claim. These dependencies make it sufficient to consider a total of six claims from the two patents: claims 1, 11, and 20 of the '424 patent (Exhibit 2) and claims 1, 10 and 22 of the '960 patent (Exhibit 3).

D. AstraZeneca Has No Evidence Of Infringement

In this Section DRL explains why there is no genuine material issue of fact regarding the alleged infringement of the six claims that need to be considered. In discussing the six claims DRL relies on one or more of three points established by the record. First, while many of the claims explicitly require omeprazole magnesium which is at least 70% crystalline, AstraZeneca has no evidence to support such a finding and, to the contrary, DRL's tests show that DRL's omeprazole magnesium is less than 1% crystalline. Second, where some of the claims require the crystallization of omeprazole magnesium by the addition of water, the evidence of record establishes that DRL obtains its omeprazole magnesium by the evaporation of the organic solvent and not by the addition of water. Third, where AstraZeneca obtained one of its patents by arguing that its process was special precisely because of the absence of organic solvents, the record establishes that DRL uses a solution containing two organic solvents to apply its subcoating.

Relying on these three points, DRL shows that at least one element is missing for each of the six claims that need to be considered -- making infringement impossible as a matter of law.

DRL addresses each of the six claims separately below.

1. AstraZeneca Cannot Prove Infringement Of The '424 Patent

a. There Is No Genuine Material Issue Of Fact Regarding Claim 1 Of The '424 Patent

There is no genuine issue of material fact regarding claim 1 of the '424 patent at least because DRL's omeprazole magnesium is not more than 70% crystalline.

During prosecution of the '424 patent AstraZeneca argued that its claims were patentable precisely because they were limited to omeprazole magnesium which was *more than 70% crystalline*. For example, in the prosecution of the '424 patent AstraZeneca argued as follows:

> In the first instance, the present compound is a magnesium salt of omeprazole having more than 70% crystallinity as determined by x-ray powder diffraction. There is no disclosure in the primary reference pertaining to magnesium omeprazole salt of degree of crystallinity of more than 70%."

Amendment and Response dated December 9, 1996, Exhibit 4, p. 3. Plainly, the 70% crystallinity limitation was front and center. Claim 1 of the '424 patent claims reflects this critical limitation and reads as follows: "An omeprazole magnesium salt having a degree of crystallinity which is higher than 70 % as determined by x-ray powder diffraction." Claim 1 '424 patent, Exhibit 2 (emphasis added).

DRL has no burden to prove that its finished ANDA capsules do not have a degree of crystallinity higher than 70%. However, tests run on Batch EC6319 showed the omeprazole magnesium in DRL's finished capsules to be amorphous material with no crystallinity above a 1% limit of detection. Exhibit 6, Answer to Interrogatory No. 9, p. 8. AstraZeneca has had a sample of DRL's finished ANDA batch capsules (Batch EC6319) since September 2007, 2nd Weinstein Decl. ¶ 6, and after testing AstraZeneca reported to the Court that there was no

evidence that the omeprazole magnesium in those capsules is more than 70% crystalline. *Id.* ¶ 8. Accordingly, AstraZeneca has no proof that claim 1 of the '424 patent is literally infringed.

There is also no evidence that claim 1 of the '424 patent is infringed under the doctrine of equivalents. As discussed above, AstraZeneca obtained its patent by arguing the inventiveness of omeprazole magnesium which was more than 70% crystalline. After distinguishing its omeprazole magnesium because it was more than 70% crystalline, AstraZeneca cannot as a matter of law argue that omeprazole magnesium which is less than 70% crystalline is the equivalent. *See Springs Window Fashions LP v. Novo Industries, L.P.*, 323 F.3d 989, 995 ("The public notice function of a patent and its prosecution history requires that a patentee be held to what he declares during the prosecution of his patent. A patentee may not state during prosecution that the claims do not cover a particular device and then change position and later sue a party who makes that same device for infringement.")

Thus, there is no genuine issue of material fact concerning the alleged infringement of claim 1 of the '424 patent, either literally or under the doctrine of equivalents.[2]

b. There Is No Genuine Issue Of Material Fact Regarding Claim 11 Of The '424 Patent

There is no genuine issue of material fact regarding claim 11 of the '424 patent at least because DRL does not obtain its omeprazole magnesium active ingredient by the addition of water.

Claim 11 of the '424 patent (Exhibit 2) is directed to a process for the manufacture of omeprazole magnesium. Claim 11 requires by its terms the step of "crystallizing magnesium

[2] Claim 1 of the '424 patent is a claim to a product. As a matter of law, AstraZeneca's *product* claims can only be infringed if DRL's actual *finished capsules* meet the elements of those claims when DRL's *product* is in the United States. *Deepsouth Packing Co. v. Laitram Corp*, 406 U.S. 518, 527, 92 S. Ct. 1700, 1706 (1972) ("[I]t is not an infringement to make or use a patented product outside of the United States.")

omeprazole by the addition of water". Exhibit 2, '424 patent claim 11, step "c". DRL does not crystallize omeprazole magnesium by the addition of water. 2d Brittain Decl. ¶¶ 50-51. Rather, DRL prepares its solid omeprazole magnesium from an organic solution by evaporating the organic solvent in a specialized device called an Agitated Thin Film Drier (an "ATFD"). 2nd Brittain Decl. ¶ 50. Because DRL does not obtain its omeprazole magnesium active ingredient by the addition of water it is impossible for AstraZeneca to prove infringement of claim 11. *Laitram*, 939 F.2d at 1535.

Significantly, DRL's process is similar to a prior art process that AstraZeneca distinguished in order to obtain its '424 patent. Specifically, during prosecution the Examiner rejected the application for the '424 patent as obvious over U.S. Patent 4,738,974 ("the '974 patent", Exhibit 7). *See*, Exhibit 8, Supplemental Amendment dated October 1, 1998, p. 2 (stating that the purpose of the Supplemental Amendment was to address the rejection based on the '974 patent). To overcome the rejection, AstraZeneca said in no uncertain terms that its claimed process was special precisely because it first used an aqueous alcohol solvent to put omeprazole into solution and then the process used a different solvent, i.e., water to recover the crystalline omeprazole magnesium:

> A further distinguishing feature of the claimed process is the use of an aqueous alcohol solvent, e.g., methanol, to put omeprazole in solution and the subsequent use of a different solvent, i.e., water, to recover the crystalline magnesium omeprazole salt from solution. In contrast, the process of Example 6 of the '974 patent uses methanol as the sole solvent throughout the process.

Exhibit 8 at p. 5 (emphasis added); In continuing to distinguish its claimed invention, AstraZeneca went so far as to describe the claimed use of "different solvents" as an "important contribution":

> The use of different solvents as part of the controlled crystallization step of the '342 application is an important

> contribution to the recovery of crystals of the claimed magnesium omeprazole salt that are suitable as pharmaceutical substances.

Exhibit 8 at p. 5 (emphasis added);

Of crucial importance here, DRL's process, which relies on evaporating the organic solvent to obtain the omeprazole magnesium, is similar to Example 6 of the '974 patent. 2nd Brittain Decl. ¶ 51. Like Example 6 of the '974 patent, DRL's process relies on the evaporation of the organic solvent -- not the addition of water -- to obtain omeprazole magnesium. 2nd Brittain Decl. ¶¶. 50-51. After distinguishing the evaporation-based process of the prior art, AstraZeneca cannot as a matter of law argue that DRL's evaporation-based process meets the element of "crystallizing magnesium omeprazole by the addition of water" either literally or under the doctrine of equivalents. *See Springs Window Fashions*, 323 F.3d at 995.

Thus, there is no genuine issue of material fact concerning the alleged infringement of claim 11 of the '424 patent, either literally or under the doctrine of equivalents.

c. There Is No Genuine Issue Of Material Fact Regarding Claim 20 Of The '424 Patent

There is no genuine issue of material fact regarding claim 20 of the '424 patent at least because DRL does not obtain its omeprazole magnesium active ingredient by the addition of water.

Claim 20 of the '424 patent claims a process for the manufacture of omeprazole magnesium where the improvement is stated to be "separating inorganic salts from the reaction mixture prior to the crystallization step by the addition of water." Exhibit 2, '424 patent, claim 20 (emphasis added). Thus, the claimed process requires a "crystallization step by the addition of water." 2nd Brittain Decl., ¶35. As discussed above with respect to claim 11 of the '424 patent, DRL's process obtains omeprazole magnesium by evaporating the organic solvent and not by the addition of water. 2nd Brittain Decl., ¶¶ 50-51. Thus, as with claim 11 of the '424

patent, there is no genuine issue of material fact regarding the alleged infringement of claim 20 of the '424 patent, either literally or under the doctrine of equivalents.

2. AstraZeneca Cannot Prove Infringement Of The '960 Patent

a. There Is No Genuine Issue Of Material Fact Regarding Claim 1 Of The '960 Patent

There is no genuine issue of material fact regarding claim 1 of the '960 patent at least because DRL's omeprazole magnesium is not more than 70% crystalline.

Unlike the '424 patent, the claims of the '920 patent are directed to specific oral formulations of omeprazole magnesium and processes for making those formulations. 2nd Brittain Decl. ¶ 17. Nonetheless, as it did in the prosecution of the '424 patent, AstraZeneca argued in the prosecution of the '960 patent that its claims were special, at least in part, because they were limited to omeprazole magnesium which was at least 70% crystalline:

> In the first instance, the instant oral formulation as presently claimed provides a core containing a magnesium omeprazole salt form with at least 70% crystallinity which advantageously affords greater stability and manufacture of coated tablets with enhanced acid resistance neither of which property is available or even suggested by the prior art disclosure of omeprazole magnesium salts.

Amendment and Response dated October 7, 1996, Exhibit 5, p. 5 (emphasis added); 2nd Brittain Decl. ¶ 49. Claim 1 of the '960 patent incorporates this critical limitation because among other limitations it is limited to an oral formulation comprising "a core containing a magnesium salt of omeprazole said salt having more than 70% crystallinity. . . . " Exhibit 3, '960 patent, claim 1 (emphasis added).

As discussed above, tests run on Batch EC6319 showed the omeprazole magnesium in DRL's finished capsules to be amorphous material with no crystallinity above a 1% limit of detection. Exhibit 6, Answer to Interrogatory No. 9, p. 8. After distinguishing its alleged

invention on the basis of the 70% crystalline limitation, AstraZeneca cannot as a matter of law argue the equivalency of Omeprazole magnesium which is less than 70% crystalline. *Springs Window Fashions*, 323 F.3d at 985.

Thus, there is no genuine issue of material fact concerning the alleged infringement of claim 1 of the '960 patent, either literally or under the doctrine of equivalents.[3]

b. There Is No Genuine Issue Of Material Fact Regarding Claim 10 Of The '960 Patent

There is no genuine issue of material fact regarding claim 10 of the '960 patent at least because DRL's omeprazole magnesium is not more than 70% crystalline and also because DRL's process for making its capsules is not conducted in the absence of organic solvents.

Claim 10 of the '960 patent is a process claim that includes the limitation of "forming a core material containing magnesium omeprazole salt said salt having at least 70% crystallinity. . . ." Exhibit 3, '960 patent, claim 10 (emphasis added). AstraZeneca cannot prove infringement of claim 10 of the '960 patent, either literally or under the doctrine of equivalents, because AstraZeneca has no evidence that DRL forms a core where the omeprazole magnesium is "at least 70% crystalline".

Moreover, AstraZeneca obtained this claim by arguing that its "novel water-based process" was "environmental friendly through the absence of organic solvents." Exhibit 5, Amendment and Response dated October 7, 1996, p.8 (emphasis added). DRL's process is the exact opposite because DRL applies its sub-coating layer with a solvent-based process that uses a mixture of two organic solvents, methanol and methylene chloride. 2nd Brittain Decl. ¶¶ 42, 53.

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[3] Claim 1 of the '960 patent is a claim to a *product*. Like claim 1 of the '424 patent, claim 1 of the '960 patent can only be infringed if DRL's actual *finished capsules* meet the elements of the claim when DRL's *product* is in the United States. *Deepsouth*, 406 U.S. at 527, 92 S. Ct. at 1706.

AstraZeneca's representations to the Patent Office made it clear that AstraZeneca distinguished its claimed process from processes which rely on organic solvents. 2nd Brittain Decl. ¶¶ 24-26. Because AstraZeneca disclaimed the use of organic solvents to obtain its patent, DRL's organic solvent-based process cannot as a matter of law be found to infringe. *See Springs Window Fashions*, 323 F.3d at 985.

Thus, there is no genuine issue of material fact concerning the alleged infringement of claim 10 of the '960 patent, either literally or under the doctrine of equivalents.

c. There Is No Genuine Issue Of Material Fact Regarding Claim 22 Of The '960 Patent

Finally, there is no genuine issue of material fact regarding claim 22 of the '960 patent at least because DRL's omeprazole magnesium is not more than 70% crystalline.

Claim 22 of the '960 patent is a product claim that also requires a core containing omeprazole magnesium which is more than 70% crystalline. Exhibit 3, claim 22 ("An improved oral pharmaceutical composition . . . wherein the improvement comprises magnesium omeprazole salt having more than 70% crystallinity. . . ." (emphasis added). As discussed above, there is no basis in the record to conclude that the crystallinity of the omeprazole magnesium in DRL's capsules is more than 70%. Moreover, after relying on the crystallinity limitation to obtain its claim, AstraZeneca cannot argue that crystallinity less than 70% is the equivalent of the 70% crystallinity required by the claims.

Thus, there is no genuine issue of material fact concerning the alleged infringement of claim 22 of the '960 patent, either literally or under the doctrine of equivalents.[4]

[4] Because claim 22 of the '960 patent is a product claim, it can only be infringed if DRL's actual *finished capsules* meet the elements of the claims when DRL's *product* is in the United States. *Deepsouth*, 406 U.S. at 527, 92 S. Ct. at 1706.

IV. CONCLUSION

For the foregoing reasons, DRL submits that there is no genuine issue of material fact regarding the alleged infringement of any claim of the patents-in-suit and DRL respectfully requests that the Court grant DRL a summary judgment that DRL does not infringe United States Patent 5,900,424 or United States Patent 5,690,960.

Dated: July 9, 2008

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on this 9th day of July, 2008, I caused a true and correct copy of DRL DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF DRL'S MOTION FOR SUMMARY JUDGMENT to be served upon counsel for AstraZeneca in the following manner:

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